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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/308,295	Applicant(s) Clark Et al
Examiner Nirmal. S. Basi	Art Unit 1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 12, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

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DETAILED ACTION

1. Amendment filed 4/12/01 (paper number 7) has been entered. The declaration of Abbot F. Clark, filed 4/12/01(paper number 6) has been considered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found 5 in a prior Office action (10/13/00, paper number 4).

Response to Amendment

Claim Rejection, 35 U.S.C. 112

3. Claims 1-5 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite 10 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record in the office action of 10/13/01, paper number 4 .

Applicants submit a declaration by Abbot F. Clark to explain why the terms “aberrant alternate splice form of human glucocorticoid receptor (GR β)”, “genetic changes” and “altered GR β expression” and “changes outside” are not indefinite. Abbot F. Clark states, “An “aberrant 15 alternative slice form of the human glucocorticoid receptor (GR β)” is defined as any different oligonucleotide sequence for GR β that is due to a different post-transcriptional splicing event(s) compared to what has been documented in the above references”. Applicants arguments have been fully considered but not found persuasive. Aberrant means deviating from normal.. Therefore without reference to what form of the GR β is considered normal the metes and bounds 20 of the claim can not be determined. Clark compares “aberrant alternative slice form” to “what

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has been documented in the above references". Clark does not specifically disclose what structure of GR β is normal. Further, without an indication of what is the structure of the GR gene it is not clear what would be the defects in said gene. The claim should refer to GR gene and GR β by SEQ ID NO: identifier.

5 As pertaining to "genetic changes" Abbot F. Clark states, "The term genetic changes" is well known by those skilled in the art", and then mentions there are numerous examples of diseases associated with genetic changes and how they can be measured. Applicants arguments have been fully considered but not found persuasive. Applicants nor Abbot F. Clark provide no clear definition of "genetic changes", only examples, so as to allow the metes and bounds of the 10 claim to be determined.

As pertaining to "altered GR β expression" Abbot F. Clark states, "Altered GR β expression" means expression of this gene product that is different from the normal", and further states the normal gene has been characterized" but does not disclose what the normal gene is. Applicants arguments have been fully considered but not found persuasive. Without reference to 15 the unaltered structure of GR gene and unaltered structure of GR β the metes and bounds of the claim can not be determined. Therefore, without the structure of the GR gene and GR β it is not clear what would be the genetic changes or alterations in said gene. Further, "altered GR β expression" can result from cell death, where there is there is no gene expression, in this instance the expression of GR β expression is still altered.

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As pertaining to "changes outside" Abbot F. Clark states "It is well known in the art that "changes outside" of the coding region of a specific gene are important in the regulation of gene expression. Applicants arguments have been fully considered but not found persuasive. It is still not clear what the are the metes and bounds of "changes"outside". What are the changes. What is considered outside? For example, is the rest of the chromosome considered outside, the cytosol considered outside, adjacent cells considered outside etc.

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Claims 2 remains rejected due to the improper Markush grouping. The claim refers to a group containing both methods and non-methods. Applicant argues, "Claim 2 is directed to a listing of assays of DNA analysis that can be used to detect GR β expression. These assays or methods; including denaturing gradient gel are specifically set forth in the specification on page 2, lines 25-29." Applicants arguments have been fully considered but not found persuasive. Denaturing gradient gel and single-stranded conformation polymorphism (SSCP) are not methods.

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Claims 1-5 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements. Applicant states, "This is accomplished by determining if a person being tested abnormally expresses GR β . This is done broadly by detecting "aberrant alternate ... (GR β) expression or defects...GR β ." Claim 1. Specific assays or methods for determining whether a person abnormally expresses GR β are set forth in claim 2". Applicants arguments have been fully considered but not found persuasive. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3)

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a conclusion that what was stated in the preamble was achieved (the method does not contain an assay step which states how and when the goal of the claim is achieved). For example, in claim 1, there is no step disclosing how the “detecting” is done, how the defect is measured, what indicates a positive or negative diagnosis, etc.

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Claim Rejection, 35 U.S.C. 112

Applicant has not specifically addressed the examiners rejection of claims 1-5 under 35 U.S.C. 112, first paragraph presented in paper number 4. Applicant states, “The invention is not directed to new methods for analyzing DNA, but diagnosing glaucoma by testing for aberrant expression of GR β ”. The examiner agrees claims 1-5 are methods of diagnosing glaucoma. 10 Applicants arguments do not overcome the rejection of record. Therefore, claims 2, 5 and amended claims 1, 3, 4 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the 15 invention, for reasons of record in the office action of 10/13/01, paper number 4.

No claim is allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time 20 policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period 5 will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Nirmal S. Basi
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June 30, 2001

Yvonne Eyler
YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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